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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,766	09/29/2006	Pierre-Alexandre Kaminski	296011US0PCT	5633
22850 7590 02/19/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER JOLKE, MICHELE K				
ART UNIT		PAPER NUMBER		
1636				
NOTIFICATION DATE		DELIVERY MODE		
02/19/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/594,766

Applicant(s)

KAMINSKI, PIERRE-ALEXANDRE

Examiner

Michele K. Joike

Art Unit

1636

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40 is/are allowed.
- 6) ☒ Claim(s) 13-18 and 21-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed November 2, 2009. Claims 1-18, 21-40 are pending, and claims 13-18, 21-32 and 40 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed August 7, 2009 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Objections

Claims 13 and 16 are objected to because of the following informalities: In claim 13, "M312" in line 5 should be "M132". Claim 16 is a duplicate of claim 15. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language is inconsistent in claim 17. If the protein comprises SEQ ID NO: 2, it can consist of SEQ ID NO: 2. It is unclear from the claim language if modifications

from claim 13 to SEQ ID NO: 2 are contemplated, so a protein comprising SEQ ID NO: 2 means that the sequence can be longer than the sequence in SEQ ID NO: 2, but will still have the sequence of SEQ ID NO: 2.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16, 21-26 and 28-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a N-deoxyribosyl transferase that is at 90% or 95% identical to SEQ ID NO: 2 and contains the residues Y13, D77, D97, E103 and M132 and the mutation A15T, or to SEQ ID NO: 4. It also claims a N-deoxyribosyl transferase with greater activity (50% or 5 times) than SEQ ID NO: 2. Lastly, it claims a nucleic acid that encodes the protein. The claims read on a broad genus of enzymes.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the

claimed invention. In the instant case, the specification does not sufficiently describe a representative number of N-deoxyribosyl transferases by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims N-deoxyribosyl transferase by function only, without any disclosed or known correlation between the elements and their function. While it teaches conservation of residues Y13, D77, D97, E103 and M132 among other *Lactobacillus* species, it does not teach how to conserve those residues and maintain N-deoxyribosyl transferase activity, with only 90% or 95% identity to N-deoxyribosyl transferase. The specification only provides teachings of a mutation in SEQ ID NO: 2 (wt N-deoxyribosyl transferase), A15T (SEQ ID NO: 4). The alanine is not conserved in the other species, yet is obviously important to activity. Therefore, it is unclear what other mutations could be made, with the sequence still being 90% or 95% identical, but that would affect activity. While mutating the alanine to threonine appears to increase ddT and d4T activity, it is unclear what effect there would be if alanine was changed to other residues. Also, Applicants only teach an A15T mutation for increasing activity. There is no teaching of a mutation that will increase activity of N-deoxyribosyl transferase, or a teaching of other mutations that will increase ddT or d4T activity. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses one mutation of N-deoxyribosyl transferase that increases activity. Furthermore, it is unclear what the nucleic acid sequence encoding the N-deoxyribosyl transferase will be since

the protein is not defined. Applicants are not in possession of the nucleic acid sequences either.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of N-deoxyribosyl transferases by disclosing structural or functional features of N-deoxyribosyl transferase so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of N-deoxyribosyl transferases. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Response to Arguments Concerning Claim Rejections – 35 USC § 112(1)

Applicants' arguments filed on November 2, 2009 have been fully considered. The following grounds of traversal are presented:

The claims have been amended to include the structural limitations of having 90% or 95% identity to SEQ ID NO: 2., as well as the conserved residues Y13, D77,

D97, E103 and M132 and a A15T mutation. Therefore Applicants are in possession of the subject matter if claim 13.

Applicants' arguments have been fully considered but have not been found persuasive for the following reason.

While the conserved residues are included in claim 13, Applicants are not in possession of any sequence that is 90% or 95% to SEQ ID NO: 2 or 4. Little is known about the structure of N-deoxyribosyl transferase from *L. fermentum*. Applicants have stated that conserved residues Y13, D77, D97, E103 and M132 are important for activity, however they have not identified the active site or any conserved domains, or given any guidance as to the residues that can or cannot be modified other than Y13, A15, D77, D97, E103 and M132. The A15T modification increases ddT and d4T activity, but decrease dT activity when compared to the w.t. protein. It is unknown what effect other mutations will have. Can any of the residues be mutated? Applicants have stated on page 7 of the specification that it is important to conserve "certain residues". It is unclear if those residues only include Y13, D77, D97, E103 and M132, or if other residues are included. They also state that residues outside of the catalytic site can be modified, but the catalytic site is not identified. Does the catalytic site include residues 13-132? if so, then residue 15 was mutated and increased ddT and d4T activity.

Allowable Subject Matter

Claim 40 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/
Primary Examiner, Art Unit 1636

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